

**IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE**

Appln No. : 10/522,403
Applicant(s): Fumitoshi ASAI et al.
Filed : January 18, 2005
For : MEDICINAL COMPOSITION FOR
TREATING ARTERIOSCLEROSIS
Art Unit : 1614
Examiner :
Docket No. : 04833CIP/HG
Confirm. No.: 5551
Customer No.: 01933

Express Mail Mailing Label
No.: EV 478 459 869 US
Date of Deposit: May 5, 2005

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Laraine Dobies
Laraine Dobies

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by check attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

**SECOND AND SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT AND TRANSMITTAL OF ENGLISH TRANSLATION
OF PRELIMINARY EXAMINATION REPORT**

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

S I R :

This supplements the INFORMATION DISCLOSURE STATEMENT filed January 18, 2005 in which Forms PTO/SB/08A and PTO/SB/08B identify all of the references cited in the International Search Report of WO 2004/009119 A1 which is the 18-month publication of Japanese Patent Application No. 2002-209165 filed July 18, 2002 of which the present application is a Continuation-in-Part. Because priority is claimed under 35 USC 120, copies are not required. However, for the convenience of the Examiner, copies of these references are enclosed herein. A copy of the International Search Report is also enclosed herewith.

In addition, annexed hereto are copies of publications listed and in the above-identified application. No. 9 on the list below is not enclosed as this is a book which is too large to copy. Also, copies of U.S. patents are no longer required under current USPTO Rules.

In the following list numbers 1 to 6 are cited in the International Search Report and numbers 7 to 39 are identified in the specification. In addition, No. 2, WO 02/04461 is repeated as No. 21 as it is cited in the International Search Report and in the specification, as is Nos. 1 and 38. However, only one copy of the publication is enclosed.

1. EP866059(US6063806)
2. WO02/04461
3. WO94/18216(US5721219)
4. WO01/96311(US2002/0028826A1 or US2002/0061901A)
5. JP62-167791A
6. Expert Opinion on Therapeutic Patents 2001, vol.11, No.8, p1301-1327

7. Diabetes, 37, 1595 (1988)
8. Biochim. Biophys. Acta, 960, 294 (1988)
9. The Washington Manual of Medical Therapeutics, 29th Edition, by Department of Medicine, Washington University School of Medicine (1998)
10. Diabete & Metabolisme (Paris), 21, 139 (1995)
11. Drugs of the Future, 25, 171 (2000)
12. USP 4,051,141
13. USP 4,127,580
14. USP 5,955,447
15. Journal of Medicinal Chemistry, 1999, Vol. 42, p.213-220
16. USP 5,721,219
17. USP 4,529,596
18. USP 4,847,265

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19. USP 5,576,328
20. USP 5,288,726
21. WO 02/04461
22. WO 92/09561
23. USP 5,491,172
24. USP 5,633,287
25. USP 6,093,719
26. USP 6,124,309
27. USP 6,143,755
28. USP 5,120,738
29. USP 5,990,173
30. UPS 5,849,732
31. WO 96/26948
32. EP 987254 A, B
33. USP 5,475,130
34. USP 5,733,931
35. WO 96/10559
36. USP 5,990,150
37. USP 6,127,403
38. USP 6,063,806
39. USP 6,200,988

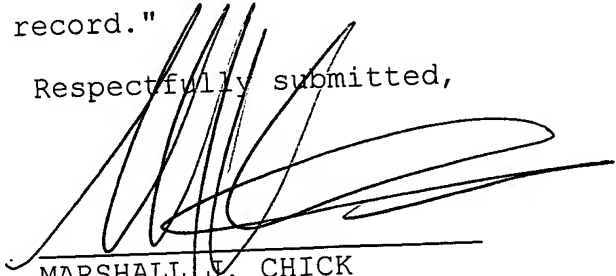
ENGLISH TRANSLATION OF PRELIMINARY EXAMINATION REPORT

Also enclosed is an English translation of the PRELIMINARY EXAMINATION REPORT issued by WIPO (Forms PCT/IB/338 and PCT/IPEA/409, 7 pages).

It is requested that the publications be considered with respect to the patentability of the present invention and that an initialed copy of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned to applicants to indicate that such publications have been considered and made "of record."

Respectfully submitted,

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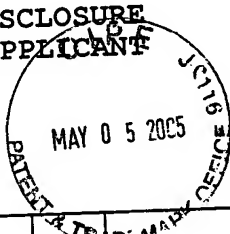
MARSHALL J. CHICK
Reg. No. 26,853

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PTO/SB/08A (08-00)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT 			Application Number	10/522,403
			Filing Date	January 18, 2005
			First Named Inventor	Fumitoshi ASAI
			Group Art Unit	1614
			Examiner Name	
Sheet 1 of 4	Attorney Docket Number		04833CIP/HG	

U.S. PATENT DOCUMENTS

Exam. Inits ¹	Cite No ¹	Document Number	Kind Code ²	Name of Patentee or Applicant	Publication Date MM-DD-YYYY	Relevant Portion
		6,063,806*	A	Kamiya et al.	05-16-2000	
		5,721,219**	A	Ingall et al.	02-24-1998	
		2002/0028826***	A1	Robl et al.	03-07-2002	
		2002/0061901***	A1	Robl et al.	05-23-2002	
		4,051,141		Castaigne	09-27-1977	
		4,127,580		Braye, Emile	11-28-1978	
		5,955,447		Ingall et al.	09-21-1999	

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Exam. Inits ¹	Cite No ¹	Offc ³	Document Number ⁴	Kind Code ⁵	Name of Patentee or Applicant	Publication Date MM-DD-YYYY	Relevant Portion	T ⁶
		EP	866059	A1	Kyoto Pharm Ind	09-23-1998		
		WIPO	WO 02/04461	A1	Sankyo Co. Ltd.	01-17-2002		
		WIPO	WO 94/18216	A1	Fisons PLC	08-18-1994		
		WIPO	WO 01/96311	A2	Bristol-Myers	12-20-2001		
		JP	62-167791	A	Morinaga Milk Ind	07-24-1987		
		WIPO	92/09561	A1	Fujisawa Pharm Co	06-11-1992		
		WIPO	96/26948	A1	Pharmacia SPA	09-06-1996		

Examiner Signature	Date Considered
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* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Place a check here if English translation is attached.

* Patent Family Member of EP 866059 A1
 ** Patent Family Member of WO 94/18216 A1
 *** Patent Family Member of WO 01/96311 A2

DATE MAILED: May 5, 2005

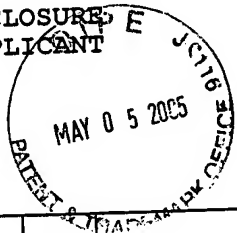
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		5,721,219		Ingall et al.	02-24-1998	
		4,529,596		Aubert et al.	07-16-1985	
		4,847,265		Badorc et al.	07-11-1989	
		5,576,328		Herbert et al.	11-19-1996	
		5,288,726		Koike et al.	02-22-1994	
		5,491,172		Lee et al.	02-13-1996	
		5,633,287		Lee et al.	05-27-1997	
		6,093,719		Bocan, Thomas M.A.	07-25-2000	
		6,124,309		Bocan, Thomas M.A.	09-26-2000	
		6,143,755		Bocan, Thomas M.A.	11-07-2000	

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		EP	0 987 254 .	A1	Kowa Co., Ltd.	03-22-2000		
		WIPO	96/10559 .	A1	Fujisawa Pharm Co	04-11-1996		
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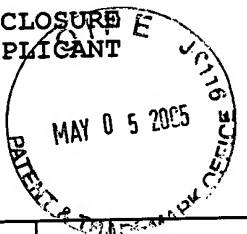
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		5,120,738		Ikawa et al.	06-09-1992	
		5,990,173		Patoiseau et al.	11-23-1999	
		5,849,732		Suzuki et al.	12-15-1998	
		5,475,130		Sato et al.	12-12-1995	
		5,733,931		Yamada et al.	03-31-1998	
		5,990,150		Matsui et al.	11-23-1999	
		6,127,403		Matsui et al.	10-03-2000	
		6,200,988		Kamiya et al.	03-13-2001	

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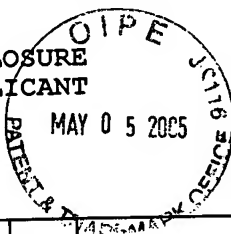
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			Group Art Unit	1614	
			Examiner Name		
Sheet	4	of	4	Attorney Docket Number	04833CIP/HG

OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		<p>CHILMONCZYK et al., "Hypolipididaemic and antiplatelet agents," Expert Opinion on Therapeutic Patents, (2001), Vol. 11, No. 8, pages 1301 to 1327, Ashley Publications, Ltd.</p> <p>English translation of International Preliminary Examination Report Forms PCT/IB/338 and PCT/IPEA/409 in International Application No. PCT/JP2003/009108.</p> <p>Gerald M. REAVEN, "Role of Insulin Resistance in Human Disease," <u>Diabetes</u>, vol. 37, December 1988, pp. 1595-1607.</p> <p>WATANABE et al., "Preventive effect of pravastatin sodium, a potent inhibitor of 3-hydroxy-3-methylglutaryl coenzyme A reductase, on coronary atherosclerosis and xanthoma in WHHL rabbits," <u>Biochim. Biophys. Acta</u>, vol. 960, (1988), pp. 294-302.</p> <p><u>The Washington Manual of Medical Therapeutics</u>, 29th Edition, by Department of Medicine, Washington University School of Medicine, (1998).</p> <p>J. DAVIGNON, "Prospects for Drug Therapy for Hyperlipoproteinaemia," <u>Diabete & Metabolisme (Paris)</u>, vol. 21, (1995) pp. 139-146.</p> <p>TANAKA et al., "Discovery of novel ACAT inhibitors as hypocholesterolemic agents: structure-activity relationships of N-(biarylmethyl)ureas and relate compounds," <u>Drugs of the Future</u>, vol. 25, (2000), pp. 171-182</p> <p>Ingall, et al., "Antagonists of the Platelet P_{2T} Receptor: A Novel Approach to Antithrombotic Therapy," <u>Journal of Medicinal Chemistry</u>, vol. 42, (1999), pp. 213-220.</p>	
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